Transapical transcatheter aortic valve replacement in patients with cardiogenic shock

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Abstract

Transcatheter aortic valve implantation (TAVI) has been introduced to treat patients at high risk for conventional surgery; however, cardiogenic shock is considered a contraindication for TAVI. The aim of the present study was to evaluate early and intermediate mortality of patients in cardiogenic shock undergoing TAVI as a rescue procedure. Patients in cardiogenic shock underwent transapical TAVI with Edwards SAPIEN (Edwards Lifesciences, Irvine, CA, USA) prosthetic valves. Preoperative, perioperative and 1-year follow-up data were analysed. Analysis included 358 patients. Preoperative cardiogenic shock was present in 21 (5.9%) patients. EuroSCORE (cardiogenic shock 73.1 ± 18.9% vs. non-cardiogenic shock 36.0 ± 18.7%; \(P < 0.0001\)) and Society of Thoracic Surgeons score (cardiogenic shock 50.8 ± 28.1% vs. non-cardiogenic shock 16.7 ± 12.2%; \(P < 0.0001\)) were significantly higher in the cardiogenic shock group, and left ventricular ejection fraction (cardiogenic shock 26.0 ± 13.1% vs. no-cardiogenic shock 51.4 ± 13.0%; \(P < 0.0001\)) was significantly lower. Thirty-day mortality was significantly higher in the cardiogenic shock group (cardiogenic shock 19% vs. non-cardiogenic shock 5%; \(P = 0.02\)) and 1-year survival significantly lower (cardiogenic shock 46% vs. no-cardiogenic shock 83%; \(P < 0.0001\)). At Cox regression, EuroSCORE was the sole determinant for follow-up mortality (odds ratio = 1.02; \(P = 0.04\)). TAVI in patients who are in cardiogenic shock is feasible. Although the early and late outcomes are encouraging, a structured strategy should be developed and further experience is needed.

Keywords: Aortic valve • Replacement • Shock

INTRODUCTION

Popularization of transcatheter aortic valve implantation (TAVI) [1–4] has widened the indication for the treatment of a severe aortic valve stenosis (AVS). In spite of the encouraging initial results achieved even in patients refused for conventional surgery [5], there is still a group of patients considered ‘too sick’ even for TAVI. In this context, severe left ventricular ejection fraction (LVEF) depression (<20%) and haemodynamic instability requiring inotropic therapy or mechanical haemodynamic support have been defined as absolute contraindications for TAVI [5].

The aim of the current study is to present the outcome of transapical TAVI in patients with acute cardiogenic shock.

MATERIAL AND METHODS

This prospective, single-institution study included patients who were treated with transapical TAVI performed at the Deutsches Herzzentrum Berlin (Berlin, Germany) between April 2008 and March 2011. Previous publications have described the training of our TAVI team and our institutional procedural policies [3, 6, 7]. Absolute contraindications to TAVI were only acute endocarditis and too large annular size. We have never considered cardiogenic shock a contraindication to TAVI. For data collection and stratification, we have defined cardiogenic shock using clinical and instrumental criteria [8]. Cardiogenic shock was diagnosed only if all the following criteria were present: unstable haemodynamic condition, requirement for increasing dosage of adrenaline and upcoming or evident multiorgan failure, including anuria and pulmonary congestion at chest radiography. Written informed consent was obtained from all patients or their representatives. The study was approved by our institutional review board.

Surgical technique

TAVI was performed through a mini left anterior thoracotomy using a left ventricular transapical route and a balloon-expandable valve (Edwards SAPIEN THV, Edwards Lifesciences, Irvine, CA, USA) of 23 or 26 mm diameter, in accordance with the indications of the manufacturer and the anatomy of the aortic root [7].

Intraoperative management of patients in cardiogenic shock

A specific strategy to optimize the outcome of cardiogenic shock patients was always applied and is summarized in the following paragraphs.

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Placement of the thoracotomy incision. The skin incision was routinely performed 2–3 cm below the mammary groove. The left ventricular apex was more easily reached, and the procedure was more comfortably performed, when the sixth or the seventh intercostal space was entered [6]. Then, to identify the position of the heart apex, the pleural cavity was opened first only 1 cm to palpate the apex by finger. If the position was not correct, the appropriate intercostal space was then entered and the previous 1-cm opening left untreated. Before this, the position of the apex was additionally determined by transthoracic echocardiography while the patient was on the operating table. This could also be identified by chest computed tomography.

Use of femoro-femoral cardiopulmonary bypass. The use of normothermic femoro-femoral cardiopulmonary bypass (CPB) was routinely considered to give more safety during the procedure. We used routinely an open surgical approach to the femoral vessels to neutralize the risk of vascular complications. We never considered a fully percutaneous approach because, in our experience, the open surgical approach does not add any negative aspect to the procedure itself and guarantees optimal access and haemostasis.

The definitive decision whether to put the patient on CPB before starting the procedure was made according to the haemodynamic state immediately before vessel puncture and surgical incision.

Transcatheter aortic valve implantation while the patient is on cardiopulmonary bypass. Introduction of the guidewires and introducers through the left ventricular apex into the left ventricle was performed while slight filling of the heart was achieved by reducing the CPB drainage to maintain left ventricular ejection and facilitate initial passage of the guide-wire through the stenotic aortic valve. If complete unloading of the heart was possible, balloon dilatation of the native valve and valve deployment were performed without rapid pacing in order to avoid possible ventricular fibrillation. If complete drainage and unloading of the heart was not possible, rapid pacing was used for balloon valvuloplasty and valve release, and the left ventricle was drained as much as possible to prevent heart distension and ventricular fibrillation. Once adequate deployment and function of the prosthesis had been achieved, the left ventricular purse strings were tied, haemostasis was achieved and an intra-aortic balloon pump was always placed transfemorally to secure greater safety and haemodynamic stability during the immediate post-operative course. Then weaning from CPB was performed.

Role of intraprocedural TEE. Trans-esophageal echocardiography (TEE) monitoring was continuously performed during all phases of the procedure.

Role of the anaesthesiologists during transcatheter aortic valve implantation. Two experienced anaesthesiologists dedicated for TAVI and with expertise in echocardiography were present in the hybrid operating room throughout the whole procedure in order to coordinate perioperative management.

Data collection and statistical analysis
All data concerning patients’ comorbidities, morbidity and mortality were prospectively collected in an electronic database and analysed.

| Table 1: Univariate analysis: comparison between continuous variables |
|-------------------|------------------|------------------|------------------|
| Variables         | Non-CS group     | CS group         | P-value          |
|                   | (mean ± SD)       | (mean ± SD)      |                  |
| Logistic EuroSCORE (%) | 36.0 ± 18.7     | 73.1 ± 18.9     | <0.0001          |
| STS score (%)     | 16.7 ± 12.2      | 50.8 ± 28.1     | <0.0001          |
| Age (years)       | 79.7 ± 7.9       | 74.5 ± 11.1     | 0.005            |
| Body mass index (kg/m²) | 27.2 ± 5.4     | 25.7 ± 5.5      | 0.3              |
| LVEF (%)          | 51.4 ± 12.0      | 26.0 ± 13.1     | <0.0001          |
| LVEDD (mm)        | 48.7 ± 7.4       | 52.8 ± 8.9      | 0.01             |
| Creatinine (mg/dl) | 1.1 ± 0.5        | 1.8 ± 0.9       | 0.006            |
| proBNP (pg/ml)    | 4567 ± 6510      | 23 628 ± 20 462 | 0.01             |
| Troponin I (µg/ml) | 0.06 ± 0.4       | 5.8 ± 9.3       | 0.08             |
| FEV1 (%)a         | 75.1 ± 22.6      | 61.4 ± 29.2     | 0.07             |
| Aortic valve area (cm²) | 0.6 ± 0.1    | 0.6 ± 0.2       | 0.9              |
| Aortic annulus (mm) | 21.9 ± 1.4      | 21.7 ± 1.5      | 0.2              |
| Grade of MI       | 1.1 ± 0.6        | 1.6 ± 0.8       | 0.01             |
| Grade of TI       | 0.6 ± 0.7        | 1.4 ± 0.9       | <0.0001          |

BNP, brain natriuretic peptide; CS, cardiogenic shock; FEV1, forced expiratory volume in the first second; LVEDD, left ventricular end-diastolic diameter; LVEF, left ventricular ejection fraction; MI, mitral insufficiency; STS, Society of Thoracic Surgeons; TI, tricuspid insufficiency.
*The pulmonary function test was performed only in 9 of 21 (43%) CS patients.

Normality of continuous variables was tested and confirmed by means of the Wilk–Shapiro test. Differences between patients with and without preoperative cardiogenic shock were tested. Multivariable analysis by means of logistic regression was performed to identify independent determinants for 30-day mortality. The Kaplan–Meier survival curves were built and equality of survival distribution between the cardiogenic shock and non-cardiogenic shock patients was tested (Mantel–Cox, Breslow, Tarone–Ware tests). Predictors of follow-up mortality were investigated by means of Cox regression. Data were analysed using SPSS Version 17.0 for Windows.

RESULTS

Patients’ characteristics
A total of 358 consecutive patients underwent transapical TAVI during the study period. Of these, 21 (5.9%) were in acute preoperative cardiogenic shock. Demographic data and comorbidity of the two groups (cardiogenic shock and non-cardiogenic shock) are presented in Tables 1 and 2.

In the cardiogenic shock group, mean international normalized ratio was 1.4 ± 0.4, aspartate aminotransferase 88.4 ± 207.4 U/l, lactate dehydrogenase 374.2 ± 348.9 U/l and γ-glutamyl transpeptidase 100.0 ± 61.0 U/l.

Four patients (19%) in the cardiogenic shock group had a preoperative diagnosis of liver cirrhosis.

Use of cardiopulmonary bypass
TAVI was performed on CPB in 47.6% (10 of 21 patients) of the patients in cardiogenic shock and in 5% (17 of 337 patients) of those without cardiogenic shock (P < 0.0001).
Intraprocedural course

Technical procedural success was achieved in all patients in cardiogenic shock. There was no conversion to open heart surgery. TEE and fluoroscopy performed after valve deployment showed that no patients from the cardiogenic shock group had relevant valve insufficiency (more than 2+ central or paravalvular leak) and none required either additional redilatation of the implanted valve or second valve implantation. Nine patients (43%) had no aortic insufficiency, six (28.5%) had a less than 1+ aortic insufficiency and six (28.5%) a less than 2+ aortic insufficiency.

Early post-operative course

There was no immediate post-operative rethoracotomy for surgical bleeding in the cardiogenic shock group. One patient (5%) developed a right haemothorax that was surgically drained more than 1 month after surgery. There were also no post-operative signs of a new neurological event. Two patients (10%) required a new pacemaker implantation because of higher-grade atrioventricular (AV) block post-operatively. There were no patients with post-operative wound problems.

Early mortality

The 30-day mortality was 19% (4 of 21 patients died) in the cardiogenic shock group and 5% (17 of 337 patients died) in the non-cardiogenic shock group (P = 0.02). All patients in the cardiogenic shock group died from multi-organ failure. No mortality directly related to the technical consideration of TAVI was encountered.

Predictors for early death

Although at logistic regression analysis EuroSCORE seemed to be the sole determinant for 30-day mortality (P = 0.03; odds ratio (OR) = 1.05 per one point increase; CI: 1.0–1.06), the multivariable model was not significantly predictive as a result of the limited number of events (omnibus test of model, P = 0.2).

Overall outcome

One-year survival was 46% in the cardiogenic shock group vs. 83% in the non-cardiogenic shock group (P < 0.0001) (Fig. 1). At Cox regression analysis (the model included age, cardiogenic shock, LVEF, EuroSCORE and Society of Thoracic Surgeons score), cardiogenic shock was not related to follow-up mortality and EuroSCORE was the sole determinant for follow-up mortality (P = 0.04; OR = 1.02 per every unit increase in EuroSCORE; CI: 1.00–1.03; Table 3).

DISCUSSION

The major findings of our study are an acceptable early mortality after TAVI in patients with cardiogenic shock and positive impact of TAVI on 1-year survival.
Treatment of cardiogenic shock

Treatment of patients with severe AVS and cardiogenic shock remains a medical and surgical challenge. Although this condition has even been considered for many years to be an absolute contraindication to surgical treatment, percutaneous approaches have been proposed [9–11].

Transcatheter aortic valve implantation and cardiogenic shock

Although TAVI in cardiogenic shock patients is feasible, perioperative results are burdened with a high mortality rate. We did not find in the present literature any report concerning the use of TAVI in cardiogenic shock patients and, for this reason, we cannot compare our outcomes.

Transcatheter aortic valve implantation vs. conventional surgery in cardiogenic shock

TAVI has increased the number of referred patients who have complex comorbidity profiles, but the assignment of this innovative technique has rarely been extended to treat patients in cardiogenic shock. Since the beginning of our experience, our institutional strategy has been to consider TAVI also for patients with acute haemodynamic instability, severely depressed LVEF and cardiogenic shock.

Paravalvular leakage: the major problem after transcatheter aortic valve implantation

The major problem of transcatheter implanted valves, in contrast to conventional valve replacement, is a high incidence of paravalvular leakage that negatively influences follow-up survival [12]. Our institutional policy is not to accept relevant paravalvular leakage after TAVI and to treat it with post-dilatation or with a second valve implant if the valve has been incorrectly positioned.

Cardiogenic shock and mortality

As shown in our results, the presence of cardiogenic shock significantly increases TAVI mortality (cardiogenic shock 19% vs. non-cardiogenic shock 5%; P = 0.02). This figure seems to be very high but is still lower than that observed after emergency conventional AV replacement at our institution. To better define our results, we have additionally analysed a contemporary cohort of patients who underwent emergency isolated conventional AV replacement at our institution. In this group, we observed a 26.0% 30-day mortality rate. These findings could justify a trial to confirm that TAVI results in better outcome.

As a result of the limited number of mortality events after TAVI, we were not able, in the present study, to design an appropriate multivariable model (logistic regression) to identify predictors for perioperative (30-day) mortality. In the Cox regression analysis, EuroSCORE had the highest predictive power for follow-up mortality. Neither the presence of cardiogenic shock nor LVEF were ‘per se’ independently related to follow-up mortality in this group of patients. At the same time, it should be emphasized that EuroSCORE in these patients is strongly influenced by the presence of cardiogenic shock. For this reason, cardiogenic shock still plays an important role in determining perioperative and follow-up mortality. In reality, mortality possibly occurs at least in the follow-up phases, as a result of the complex comorbid profile reflected in the EuroSCORE (that includes cardiogenic shock) and the findings of the Cox regression should be cautiously interpreted keeping under consideration the global critical preoperative state of these patients.

Limitations of the study

The main limitation of this observational study is the small number of patients with cardiogenic shock. Furthermore, cardiogenic shock patients are significantly younger. This is not related to our selection and may be dependent on the referral pattern. Finally, we have no control group. A comparison with an historical cohort treated with conventional surgery was not the aim of the present manuscript and could be the topic for future investigations.

Conclusions

Cardiogenic shock in patients with AVS has a dismal outcome. TAVI is a realistic life-saving option for these patients who would otherwise encounter death. A tailored strategy and a multidisciplinary approach are mandatory to achieve satisfactory results. The fact that TAVI is the ‘gold standard’ at our institution does not necessarily mean that this has to be adopted by all unless consistent and robust data are provided in the future.

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